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09/657,631	09/06/2000	Marilynn E. Etzler	23070-079820US	1727

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/657,631	Applicant(s) ETZLER ET AL.	
	Examiner Stuart Baum	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspondence addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *2,3,6-8 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,9 and 11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's election with traverse of Group III, claims 1, 4, 5, 8-9 and 11-14 including SEQ ID NO:8 encoding SEQ ID NO:10 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that searching more than one nucleic acid sequence does not add undue burden for examination purposes. This is not found persuasive because while searches are over-lapping and co-extensive, search evaluations are still divergent.

The requirement is still deemed proper and is therefore made FINAL.

Claim 1 is objected to for misspelling "mycorrihizal".

Claim 1 is objected to for reading on non-elected material.

Claim 1 is objected to for not writing out "lectin nucleotide phosphohydrolase (LNP)" the first time LNP is used in a sentence.

Claim 8 is withdrawn from consideration as it lacks anticedent basis in the recitation "NBP46 polypeptide".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-5, 8-9, and 11-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-17, 20-22,

49-50, and 52 of copending Application No. 09/129112. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to a method of modulating mycorrhizal infection comprising transforming a plant with an expression cassette comprising a LNP polynucleotide in sense orientation, wherein the LNP polynucleotide encodes a LNP polypeptide at least about 70% identical to SEQ ID NO:10 and wherein the LNP polynucleotide is SEQ ID NO:8. The expression cassette also comprises a LNP promoter all of which enhance the LNP expression thereby increasing infection of the plant by a mycorrhizal fungus, wherein the mycorrhizal fungus is *Glomus intraradices*. Claims 16-17, 20-22, 49-50, and 52 are drawn to a method of enhancing rhizobial binding to roots of a plant comprising transforming a plant with an expression cassette comprising a heterologous NBP46 polynucleotide that hybridizes to SEQ ID NO:1 or a sequence that is 80% identical to SEQ ID NO:15 operably linked to a heterologous promoter. Even though claims 1, 4-5, 8-9, and 11-14 of the present application are not identical to claims 16-17, 20-22, 49-50, and 52 of Application No. 09/129112, they are not patentably distinct because a LNP was formerly known as NBP46 (page 2, line 10) and SEQ ID NO:15 is 100% identical to SEQ ID NO:10 of Application No. 09/129112 and the method steps are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5, 9, and 11-14 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Applicant claims a method of modulating mycorrhizal infection comprising transforming a plant with an expression cassette comprising a LNP polynucleotide in sense orientation, wherein the LNP polynucleotide encodes a LNP polypeptide at least about 70% identical to SEQ ID NO:10 and wherein the LNP polynucleotide is SEQ ID NO:8. The expression cassette also comprises a LNP promoter all of which enhance the LNP expression thereby increasing infection of the plant by a mycorrhizal fungus, wherein the mycorrhizal fungus is *Glomus intraradices*.

The Applicants do not identify structural features unique to the LNP protein, the functional domains of the protein nor the overall function of the protein. The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. Given the lack of description for the LNP protein, it remains unclear what features identify a LNP protein, including a LNP gene encoding a LNP protein with at least about 70%

identity to SEQ ID NO:10. Since a LNP protein has not been described by specific structural features or by specific function, the specification fails to provide an adequate written description to support the generic claims.

Claims 1, 4-5, 8-9, and 11-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited a method of decreasing the mycorrhizal infection of *Lotus japonicus* by *Glomus intraradices* comprising transforming *L. japonicus* with a construct comprising the *L. japonicus* lectin nucleotide phosphohydrolase (LNP) in antisense orientation operably linked to the CaMV 35S promoter and terminator does not reasonably provide enablement for claims broadly drawn to a method of modulating mycorrhizal infection in any plant comprising transforming any plant with any LNP polynucleotide wherein the LNP polynucleotide encodes an LNP polypeptide at least about 70% identical to SEQ ID NO:10 all of which are in sense orientation operably linked to any LNP promoter for the purpose of enhancing expression of the LNP polynucleotide thereby increasing infection of the plant by any mycorrhizal fungus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to a method of modulating mycorrhizal infection comprising transforming a plant with an expression cassette comprising a LNP polynucleotide in sense orientation, wherein the LNP polynucleotide encodes a LNP polypeptide at least about 70% identical to SEQ ID NO:10. The instant specification, however, fails to provide guidance for which amino acids of SEQ ID NO:2 can be altered and to which other amino acids, and which amino acids must not be changed, to maintain activity of the encoded protein. The specification

also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional enzyme.

It cannot be predicted by one of skill in the art that nucleic acids encoding protein with 70% identity with *L. japonicus* LNP will still maintain the same activity as the *L. japonicus* LNP protein. Bowie et al (1990, Science 247:1306-10) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of the protein to fold into unique three-dimensional structures that allows it to function and carry out the instructions of the genome. The cited reference also teaches that the prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex (pg 1306, left column). Bowie et al teach that while it is known that many amino acid substitutions are possible in any given protein, the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three-dimensional structure/function relationship, and these regions can tolerate only conservative substitutions or none at all (pg 1306, right column). The sensitivity of proteins to alterations in even a single amino acid in a sequence is exemplified by McConnell et al (2001, Nature 411 (6838):709-713), who teach that the replacement of a glycine residue located within the START domain of either the PHABULOSA or PHAVOLUTA protein receptor with either an alanine or aspartic acid residue, alters the sterol/lipid binding domain. This change renders the protein constitutively active and therefore creates a dominant mutation which has a drastic alteration in phenotype compared to wild-type *Arabidopsis* plants.

Given the unpredictability of determining the function of an isolated nucleic acid other than SEQ ID NO:8 on the basis of its nucleotide sequence alone and the unpredictability that a selected nucleic acid encoding a protein with 70% identity to SEQ ID NO:10 will maintain the activity of a polypeptide of SEQ ID NO:10 for the reasons stated above; given the lack of working examples and guidance of selecting a LNP nucleic acid encoding a LNP protein having at least 70% identity to SEQ ID NO:10 that still maintains the proper activity of an endogenous LNP protein from *L japonicus*; given the state of the prior art which does not provide further guidance about LNP genes in regards to which domains of the protein are essential to maintain the proper enzymatic and/or receptor activity; and given the breadth of the claims which encompass a multitude of sequences that have not been exemplified, it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-5, 8-9, and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Etzler et al (18 February, 1999, WO99/07223).

The claims are drawn to a method of modulating mycorrhizal infection comprising transforming a plant with an expression cassette comprising a LNP polynucleotide in sense orientation, wherein the LNP polynucleotide encodes a LNP polypeptide at least about 70%

identical to SEQ ID NO:10 and wherein the LNP polynucleotide is SEQ ID NO:8. The expression cassette also comprises a LNP promoter all of which enhance the LNP expression thereby increasing infection of the plant by a mycorrhizal fungus, wherein the mycorrhizal fungus is *Glomus intraradices*.

Etzler et al teach a method of transforming a plant with a NBP46 polylnucleotide operably linked to a root specific promoter. The Applicants from the present application disclose that LNP was formerly called NBP46 or DB46 (page 2, line 10). Given that the methods steps from both the present application and Etzler et al are the same, it would be an inherent property of LNP to modulate infection of mycorrhizal fungi and therefore, Etzler et al anticipate the present invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 11, and 12 and all subsequent dependent claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation "modulating". Applicant is requested to explicitly state how mycorrhizal infection of a plant is changed.

Claim 11 is indefinite in the recitation "wherein the promoter is linked to the LNP polynucleotide in a sense orientation". Amending the claim to recite --wherein the LNP polynucleotide is operably linked to the promoter in sense orientation-- will rectify the rejection.

Claim 12 is indefinite in the recitation "expression of the LNP polynucleotide is enhanced". This is a relative term which does not set forth the metes and bounds of the expression levels of the LNP protein. How much expression is required to increase infection of mycorrhizal fungi?

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the legal analyst, Kim Davis, whose telephone number is (703) 305-3015.

Stuart Baum Ph.D.

July 9, 2002

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600